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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,181	02/26/2002	Ruth Gimeno	MNI-220	8227

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
MAYER, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,181	GIMENO ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 30-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-22-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.0

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV in the reply filed on June 9, 2005 is acknowledged. The traversal is on the grounds that Group IV and Group XIII should be examined together. This is not found persuasive because a method of identifying a compound for treating a metabolic disorder and the method of identifying a compound that modulates an adipocyte activity is not necessarily co-extensive because each method is divergent in materials and steps.

The requirement is still deemed proper and is therefore made FINAL. Clarification has been requested on the second restriction requirement and if the previous restriction requirement had been vacated. While it was not explicitly stated that the 1st restriction requirement was vacated, it was implied in the statement asserting that the first restriction requirement by a different examiner was deemed to be incomplete, hence the need for a second restriction requirement. Applicants have also asserted that the present restriction requirement is incomplete because not all of the claims are put into groups. The examiner respectfully disagrees with this assertion, because as is noted, for example, after Group IV:

> **"Note:** If any of groups III-IV is elected, applicant is required to select a specific metabolic disorder to be treated selected from one of claims 25-28 that will be examined along with the elected group."

It is noted that Applicants have actually failed to elect one specific metabolic disorder from claims 25-28 to be examined along with the elected Group IV, claims 24 and 29 and in this point, the election is not fully responsive. However, upon reconsideration,

the examiner has decided that rejoinder is reasonable and thus claims 24-29 will be examined in this application.

Status of the Claims

2. Claims 1-72 are pending in this application. Claims 1-23 and 30-72 are withdrawn from further consideration as they are drawn to non-elected subject matter. Claims 24-29 are under examination in this Office action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on February 22, 2002 has been considered by the examiner. See signed and attached PTO-1449.

Claim Objections

4. Claim 24 is objected to because of the following informalities: The claim contains non-elected subject matter which is drawn to nucleic acid expression of 14273. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Glucksmann et al. (US 6,395,877 B1). Glucksmann et al. teach that 14273 is a G-protein coupled receptor that participates in signaling pathways, where signaling pathways are defined as modulators (stimulators or inhibitors) of cellular function/activity when a ligand binds to the 14273 protein (see column 6, lines 45-50). Furthermore, it is taught that the 14273 receptor protein is expressed in brain, heart, skeletal muscle, thymus, prostate, uterus and placenta cells (see column 6, lines 58-60) and that specifically it seems that the receptor polypeptides of 14273 have been been linked to cardiovascular diseases. Finally, screening methods are taught for compounds that modulate the activity of the receptor polypeptides (14273) (see column 18, lines 65-67, through to column 19, lines 1-6) and an example of one of the many methods described for the identification of polypeptide modulators is described as follows (column19, lines 33-51):

> "The receptor polypeptides can be used to screen a compound for the ability to stimulate or inhibit interaction between the receptor protein and a target molecule that normally interacts with the receptor protein. The target can be a ligand or a component of the signal pathway with which the receptor protein normally interacts (for example, a G-protein or other interactor involved in cAMP or phosphatidylinositol turnover and/or adenylate cyclase, or phopholipase C activation). The assay includes the steps of combining the receptor protein with a candidate compound under conditions that allow the receptor protein or fragment to interact with the target molecule, and to detect the formation of a complex between the protein and the target, such as any of the associated effects of signal transduction, such as ion flux, G-protein phosphorylation, cyclic AMP or poshphatidylinosotol turnover, and adenylate cyclase or phospholipase C activation."

Thus, Gluckmann et al. teach the method as described in the instant claims because the intended use of the compound identified by the described method, whether it is to

treat a cardiovascular disease or a metabolic disease is of no consequence and does not, in this instance carry any patentable weight since the method steps are exactly the same. Thus, the methods described by Gluckmann et al. are inherently the same methods those being claimed.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

6. Claims 24-28 rejected under 35 U.S.C. 102(e) as being anticipated by Feder et al. (US 2003/0022186 A1). Feder et al. teach a human G-protein coupled receptor that is 100% identical to the 14273 G-protein coupled receptor (SEQ ID No: 2) of the instant application (see PTO sequence alignment). Furthermore, a method of screening candidate compounds capable of modulating activity of the G-protein coupled receptor is taught, whereby the method consists of contacting a test compound with a cell or tissue that expresses the G-protein coupled receptor polypeptide and then selecting those compounds which do in fact modulate the activity of the G-protein coupled receptor polypeptide (see claim 10 and p. 23-24, paragraph [0241]). Thus inherently, Feder et al. teach the method of the instant claimed methods because the intended use of the compound of the instant claims for treating various metabolic disorders is a

inherent property of the screening methods because you are using the exact same polypeptide.

7. Claims 24-29 rejected under 35 U.S.C. 102(b) as being anticipated by Glucksmann et al. (WO 00/00611, cited on the IDS of Feb. 2, 2002). Glucksmann et al. teach that 14273 is a G-protein coupled receptor and methods of screening for compounds that modulate the activity of the receptor polypeptide are disclosed (see p. 5, lines 10-18) and that these assays that involve any of the known G-protein coupled receptor functions or activities or properties are useful for diagnosis and treatment of G-protein coupled receptor-related conditions (see p. 26, lines 5-8 and lines 21-26, p. 31, lines 12-17; and claims 1 and 20). Thus Gluckmann et al. teach that these assay methods are useful in treating any 14273 G-protein coupled receptor-related condition which inherently meets the limitations of the claims where the assay and screening methods are useful for treating metabolic conditions.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
16 June 2005

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653